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| 10/713,898      | 10/18/2002  | David C. Schwartz    | 960296.99047        | 4216             |

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EXAMINER

MUMMERT, STEPHANIE KANE

ART UNIT

PAPER NUMBER

1637

NOTIFICATION DATE

DELIVERY MODE

04/17/2008

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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### Office Action Summary

**Application No.**

10/713,898

**Applicant(s)**

SCHWARTZ ET AL.

**Examiner**

STEPHANIE K. MUMMERT

**Art Unit**

1637

**Period for Reply** -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 27 December 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 21 and 23-27 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 21 and 23-27 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-8508)
- Paper No(s)/Mail Date \_\_\_\_\_

- 4) ☐ Interview Summary (PTO-413)
- Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

Applicant's amendment filed on December 27, 2007 is acknowledged and has been entered. Claim 22 has been canceled. Claims 21 and 23-27 are pending.

Claims 21 and 23-27 are discussed in this Office action.

All of the amendments and arguments have been thoroughly reviewed and considered but are not found persuasive for the reasons discussed below. Any rejection not reiterated in this action has been withdrawn as being obviated by the amendment of the claims. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

**This action is made NON-FINAL due to reformulation of rejections and clarification of the explanation of priority afforded to specific claims.**

### **Previous Rejections**

#### ***Claim Interpretation***

The term 'microchannel' is being given the broadest reasonable interpretation in light of the specification. The term is not explicitly defined in the specification and the term is instead described in general terms and includes preferred embodiments. For example, the specification notes "the present invention fixes and straightens polymeric molecules using a channel sized to provide laminar flow of a liquid along a channel length, the channel having at least a first wall providing electrostatic attraction to the polymeric molecule" (paragraph 13 of PgPub). The

specification also teaches “the channel may include a region of varying cross-section to promote a gradient in the laminar flow rate” (paragraph 29 of PgPub). Finally, regarding more specific dimensions, the specification notes “in one embodiment, the cross-sectional width of the microchannel is 50 micrometers and is preferably less than 100 micrometers. More generally, it is believed that the width will be between one and one hundred times the straightened length 40 of the polymeric molecule” (paragraph 51 of PgPub). While this portion of the specification suggests specific size of the microchannel, this teaching does not reach to the level of a specific definition of the size at which a channel of the invention is a microchannel. Therefore, as the term has no specific size limitations associated with it, the term is being given the broadest reasonable interpretation and is being interpreted as reading on application of the method to a ‘channel’ of any size.

Regarding the term ‘wall’, the term is not given a specific definition and therefore is being given the broadest reasonable interpretation in light of the specification and is being interpreted as reading on DNA affixed or attached to any surface, including a rounded particle or bead.

### ***New Grounds of Rejection***

The statement of lack of support in the priority documents has been adjusted in response to the request from Applicant and to correct a typographical error for application no. 09/962802, which corresponds to US Patent 6,610,256.

The art rejections have also been reformulated to remove the Miyachi reference and to clarify the grounds for obviousness. The rejection of claim 23 has been corrected and is properly rejected under 35 USC 103 in view of Kambara and Bensimon and not only under Kambara.

***Priority***

The later-filed application must be an application for a patent for an invention which is also disclosed in the prior application (the parent or original nonprovisional application or provisional application). The disclosure of the invention in the parent application and in the later-filed application must be sufficient to comply with the requirements of the first paragraph of 35 U.S.C. 112. See *Transco Products, Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 32 USPQ2d 1077 (Fed. Cir. 1994).

The disclosure of the prior-filed application, Application No. 09/962802 (US Patent 6610256), 08/855410 (US Patent 6294136) and 08/415710 (US Patent 5720928), fails to provide adequate support or enablement in the manner provided by the first paragraph of 35 U.S.C. 112 for one or more claims of this application. Each of these patent disclosures and claims are directed to practice of the method on a planar surface and do not disclose or otherwise provide support for the practice of the method in channel or microchannel formats as claimed in the instant specification. The only mention of channels or microchannels present in these prior filed applications is the use of a microchannel plate reader, a disclosure which does not support the method of straightening or fixing within a channel.

***Claim Rejections - 35 USC § 103***

1. Claims 21, 23-25 and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kambara et al. (US Patent 5,356,776; October 1994) in view of Bensimon et al. (US Patent 6,265,153; July 2001). Kambara teaches a method of fixing and straightening DNA molecules in a channel (Abstract).

With regard to claim 21, Kambara teaches a method of straightening and fixing polymeric molecules comprising the steps of:

(a) putting the polymeric molecules in a carrier liquid (col. 3, lines 48-57, where the terminus of the DNA is fixed and stretched via fluid flow; col. 4, lines 1-17),

(b) passing the polymeric molecules and carrier liquid through a micro-channel to promote a laminar flow of carrier liquid in the micro-channel causing the polymeric molecule to achieve a straightened configuration (Figure 8, col. 4, lines 1-17, where the terminus is labeled and the opposite terminus is bound or affixed to a particle, and the DNA affixed to the wall/particle is passed in a carrier liquid through a microchannel; see Example 4, col. 10, lines 48-65, where the dimensions of the channel are provided; liquid flow is used to fix the particle and stretch the DNA and therefore meets the limitation of a laminar flow and the polymer is straightened).

With regard to claim 24, Kambara teaches an embodiment of claim 21 further including the step of (d) optically inspecting the straightened polymeric molecule attached to the first wall (Example 4, col. 10, where following stretching in the microchannel, the DNA is optically inspected to determine the position of the label at the opposite end of the molecule, see especially lines 65-67).

With regard to claim 25, Kambara teaches an embodiment of claim 21 further wherein step (b) first causes a straightening of the polymeric molecule in the laminar flow and second causes attachment of one end of the polymeric molecule to the first wall and third causes attachment of the length of the polymeric molecule to the wall (Figure 8, col. 4, lines 1-17, where the terminus is labeled and the opposite terminus is bound or affixed to a particle, which meets the limitation of a wall attractive to the polymeric molecule, and the DNA affixed to the wall/particle is passed in a carrier liquid through a microchannel; see Example 4, col. 10, lines 48-65, where the dimensions of the channel are provided; liquid flow is used to fix the particle and stretch the DNA).

Regarding claims 21, 24 and 25, while Kambara does not teach direct attachment to the first wall of the channel, Kambara instead teaches attachment to a different wall, specifically the bead, which meets the limitation of a wall of the channel. However, the bead with the molecule attached is fixed relative to the first wall and therefore 'attaches' the polymer to the first wall. Bensimon teaches a process for aligning a macromolecule onto the surface of a support and attaching the molecule to the first wall (Abstract).

With regard to claim 21, Bensimon teaches having a first wall (col. 3, lines 11-17, where the support of Bensimon can take many forms, including beads or particles) electrostatically attractive to the polymeric molecule (col. 3, lines 58-65, where the adsorption of the macromolecule onto the surface can be controlled through surface charges and the electrostatic interactions between the surface and the molecule; col. 4, lines 52-61, where specific types of surface functionalities are described; see also col. 5, lines 4-23, for example) and causing the polymeric molecule to adhere in straightened configuration to the first wall (Example 1, col. 17,

lines 39-46, where capillary force on the DNA molecule(s) is sufficient to stretch the molecule; col. 4, lines 4-6, where it is noted that one aligned, the molecules adhere strongly to the surface).

With regard to claim 27, Bensimon teaches an embodiment of claim 21 further including the step of treating at least one wall of the microchannel to have a positive surface charge of predetermined density (col. 3, lines 58-65, where the adsorption of the macromolecule onto the surface can be controlled through surface charges and the electrostatic interactions between the surface and the molecule; col. 4, lines 52-61, where specific types of surface functionalities are described; see also col. 5, lines 4-23, for example).

With regard to claim 23, Bensimon teaches an embodiment of claim 21 further including the step of (d) applying restricting enzymes to the straightened polymeric molecule attached to the first wall (col. 12, lines 53-58, where physical mapping of genomic DNA can be carried out through a method comprising the steps of extraction, purification, cleavage with restriction enzyme followed by 'combing' on surfaces).

Regarding claim 23, Bensimon teaches that the method of physical mapping of polymeric molecules comprises thorough restriction digestion followed by fixation and elongation. However, it would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to modify the order of method steps taught by Bensimon to arrive at the claimed invention with a reasonable expectation of success. As noted in the MPEP § 2144.04 IV C, "Ex parte Rubin, 128 USPQ 440 (Bd. App. 1959) (Prior art reference disclosing a process of making a laminated sheet wherein a base sheet is first coated with a metallic film and thereafter impregnated with a thermosetting material was held to render prima facie obvious claims directed to a process of making a laminated sheet by reversing the order of the prior art process

steps.). See also *In re Burhans*, 154 F.2d 690, 69 USPQ 330 (CCPA 1946) (selection of any order of performing process steps is *prima facie* obvious in the absence of new or unexpected results); *In re Gibson*, 39 F.2d 975, 5 USPQ 230 (CCPA 1930) (Selection of any order of mixing ingredients is *prima facie* obvious.).” Therefore, in the absence of new or unexpected results, it would have been *prima facie* obvious to one of ordinary skill in the art to adjust the order of the method steps taught by Bensimon to arrive at the claimed invention with a reasonable expectation for success.

Further regarding claim 21, neither Kambara or Bensimon explicitly teach the term of “detaching” the first wall from the microchannel. Bensimon teaches analysis of the straightened polymeric molecules stretched out on a slide or other planar surface (Example 3, col. 19, lines 21-26, where the adhered molecules are analyzed after removal of the coverslip; see also Figures 7-9). Therefore, it would have been *prima facie* obvious to remove the slide or planar support with the straightened molecules attached for further processing, achieving the limitation of the claim as recited.

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to have applied the teachings of Bensimon to the method of DNA stretching and analysis taught by Kambara to arrive at the claimed invention with a reasonable expectation for success. Kambara teaches a method comprising affixing one end of a DNA molecule to a bead, which comprises a broad interpretation of a wall of a channel, places the DNA in a channel that captures the polymer to a wall of the channel and stretches the DNA using fluid flow, or laminar flow. Bensimon teaches a very similar method of DNA analysis, however in this case an end of the DNA is fixed and the DNA is aligned along the length of a wall, which may comprise